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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/593,693

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Hirofumi Matsuzaki

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EXAMINER

ABDI, AMARA

ART UNIT

PAPER NUMBER

2624

MAIL DATE

DELIVERY MODE

09/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/593,693 | MATSUZAKI, HIROFUMI | |
| | Examiner | Art Unit | |
| | AMARA ABDI | 2624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/20/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1, 3-4, and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Greenway et al. (US 7,433,025).

(1) Regarding claims 1 and 4:

Greenway et al. teach a protein crystal detection apparatus (col. 1, line 66) and method (col. 8, line 34) for detecting a protein crystal (col. 1, lines 65-67) contained in a protein solution held in a crystallization vessel (satellite well) (col. 3, line 58), the protein crystal detection apparatus comprising:

an observation stage on which a crystallization vessel (satellite well) to be observed is set (adjusting the setting by the operator) (col. 4, lines 1-5);

a camera (digital camera) (130 in Fig. 13) for photographing a plurality of cross sections of the protein solution on the observation stage at different positions in a focusing direction (acquiring multiple images at various angles) (col. 3, lines 59-60, and col. 7, lines 35-47), thereby capturing a plurality of layer images (col. 5, lines 30-32);

an observed-image storage for storing the plurality of layer images captured by the camera (col. 11, lines 37-41);

a crystal characteristic image formation part for forming a crystal characteristic image for each of the layer images (col. 11, lines 49-52) by extracting (finding) a characteristic portion of the protein crystal from each of the layer images stored in the observed-image storage (col. 11, lines 48-49);

a layer information extraction part for determining layer information for each of the layer images (analyzing and determining more information for each single image) (col. 5, lines 34-36) by digitizing the characteristic portion of the protein crystal contained in the crystal characteristic image (allowing digital image processing to occur) (col. 9, lines 6-12); and

a crystallization determination part for determining growth status of the protein crystal contained in the protein solution (detecting early stages of protein aggregation) (col. 8, line 55) based on the layer information of each layer image alone (based on the image data of each satellite well) (col. 8, lines 48-51) and correlation of the layer information between the cross sections of adjacent ones of the layer images (associating the results with the plates in the database) (col. 8, lines 54-55 and col. 11, lines 26-27).

(2) Regarding claims 3 and 6:

Greenway et al. teach the protein crystal detection apparatus of claims 1 and 4, wherein the crystallization determination part determines a presence or absence of a protein crystal (Fig. 7, col. 12, lines 56-47) and a product other than the protein crystal (crystallization catalyst) (Fig. 1, col. 1, lines 29-32).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2, 5, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenway et al. (US 7,433,025) in view of Gester et al. (6,529,612).

(1) Regarding claims 2 and 5:

Greenway et al. teach the parental claims 1 and 4. Furthermore, Greenway et al. teach the apparatus, where the layer information includes at least a number of pixels corresponding to the characteristic portion of the protein crystal (Figs. 5A, 6) (col. 10, lines 36-39) and a number of labels which are each a block of the pixels in the digital image (col.3, lines 43-46).

However, Greenway et al. do not teach explicitly that the image is a binary image.

Gester et al., in analogous environment, teach the method for acquiring, storing, and analyzing crystal images, where converting the acquired images to binary images (col. 6, lines 6-10).

It is desirable to enhance the reliability of the data inputted into the system, and to minimize technician labor. The Gester et al. approach, where converting the acquired images to binary images is to achieve this goal. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention, to apply the Gester et

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al. method, where converting the acquired images to binary images, with the Greenway et al. teaching, because such feature enhances the reliability of the data inputted into the system, and to minimize technician labor by using software template by the operator to minimize the entry of duplicative or repetitive information (col. 6, lines 21-24).

(2) Regarding claims 7 and 8:

The combination Greenway et al. and Gester et al. teach the parental claims 2 and 5. Furthermore, Greenway et al. teach the protein crystal detection apparatus, wherein the crystallization determination part determines a presence or absence of a protein crystal (Fig. 7, col. 12, lines 56-47) and a product other than the protein crystal (crystallization catalyst) (Fig. 1, col. 1, lines 29-32).

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cvetkovic et al. teach the quantifying anisotropic solute transport in protein crystal using 3-D laser scanning confocal microscopy visualization (biotechnology and bioengineering, vol. 86, No. 4, May 20, 2004).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMARA ABDI whose telephone number is (571)270-1670. The examiner can normally be reached on 8:00 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Samir Ahmed can be reached on (571) 272-7413. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AMARA ABDI/
Examiner, Art Unit 2624

/Samir A. Ahmed/
Supervisory Patent Examiner, Art Unit 2624